June 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

re: Docket No. 99D-0557 99 JUN 28 A10:2

Sir/Madam,

The Foundation appreciates the opportunity to comment on the "Guidance for Industry: Public Health issues Posed by the Use of Nonhuman Primate Xenografts in Humans" which was published in the Federal Register on April 6, 1999. The Foundation provides funding to unique scientific and animal welfare projects, and works with scientists around the world.

The Foundation supports the Food and Drug Administration guidance that clinical protocols proposing the use of nonhuman primates not be submitted. The Administration correctly notes that there are serious public health safety concerns, specifically "significant infectious disease risk..." The FDA might have also noted that safer, less costly, more effective, and humane alternatives to xenografts exist to address the "critical shortage of human grafts available for transplant."

The Foundation believes that FDA should immediately also announce a prohibition on acceptance and review of clinical trials involving pig or other animal xenografts. All of the risks associated with primates are also associated with pigs.

The guidance states that the "agency notes that measures taken during the production of some nonhuman primate xenografts products, such as extensive preclinical xenotransplant product testing for infectious agents, genetic engineering, enclosure of the product in a semipermeable barrier, and/ or the use of well-characterized cell lines which have been handled in a manner to avoid the introduction of new pathogens, could potentially provide greater control of infectious disease risks. The agency specifically solicits comments on the potential for such measures, alone or in combination, to substantially reduce the risks posed by nonhuman primate xenotransplantation."

Leonard X. Bosack and
Bette M. Kruger
Charitable Foundation

C100
8422 154th Avenue N.E.
Redmond, WA 98052
(425) 556-9392

99D-0557

Given the recognition that "infectious agents which result in persistent latent infections may remain dormant for long periods before causing clinically identifiable disease" and that infectious agents "may not be readily identified with current diagnostic" tools, pig and primate xenografts should clearly be prohibited in clinical trials. The Administration asks if there is the "potential" to reduce the risks through various methods. Indeed there may be, but at what cost?

The proposed tissue registry and archive would cost taxpayers over $1.5 million each year. Raising animals for xenografts, and transplanting the organs to humans, is more costly than human-to-human organ transplants. If there are safe alternatives to xenografts that are more efficient, should taxpayer dollars be directed to exploring the "potential" to "reduce" extremely grave public health risks?

Preventative health measures would greatly reduce the number of U.S. citizens requiring treatment of diseased organs. This approach is more cost effective but also improves the quality of life for individuals who are saved from the physical and psychological impact of disease treatment.

There is great "potential" to dramatically increase organ donations. There are highly successful European programs that can serve as models for the U.S. Research into how to improve human-to-human organ transplant success rates should also be conducted since many individuals on the organ transplant waiting lists need to replace a transplanted organ that has failed.

The Administration should not direct funding to research on xenografts until every preferable option has been examined. Funding and regulatory programs and oversight should be redirected from examination of xenografts to preventative health care, improving human-to-human organ transplant technique, and increasing the number of human donors. Research into, and trials of, xenografts, whether pig or primate, should be prohibited.

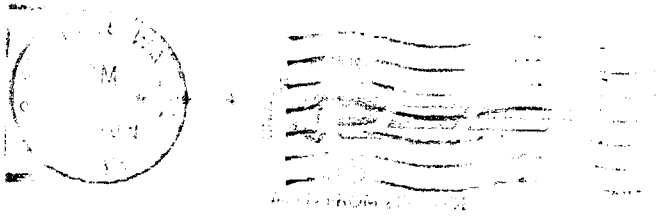
Thank you for your consideration.

Sincerely,

Scott VanValkenburg
Program Manager

Leonard N. Bosack and
Belle M. Krueger
Charitable Foundation

8422 15th Avenue N.E.
Redmond, WA 98052



DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852